

## **REMARKS**

Applicants affirm the election of Group I, claims 1-11 and 31-35, as listed in the present Office Action. Non-elected claims 12-30 have been canceled without prejudice to their further prosecution in any continuation or divisional application.

Claim 2 has been canceled and incorporated into claim 1. Claim 3 has been amended to ensure consistency with amended claim 1. Amendment of claim 8 is supported by the specification, for example, at page 19, lines 12-15, and page 26, line 20 through page 27, line 34. No new matter has been added. Claims 1, 3-11, and 31-35 are present and active in the application.

## **INTERVIEW SUMMARY**

Applicants thank Examiners Ware and Naff for the helpful discussion with Applicants' representatives on July 26, 2006. During this discussion, independent claim 1 was reviewed with respect to the art of record and proposed claim amendments were discussed.

## **REQUEST FOR RECONSIDERATION**

The invention is in the field of methods and compositions for the sterilization of materials and apparatus that may have been contaminated with infectious agents and for detection of those agents. In particular, the invention relates to methods for the inactivation and detection of transmissible spongiform encephalopathy (TSE) agents and provides compositions for degrading and detecting TSE located on or within infected materials.

Transmissible spongiform encephalopathies (TSEs) are a group of fatal neurological diseases that include Creutzfeld-Jacob disease (CJD) and Kuru in humans, bovine spongiform encephalopathy (BSE) in cattle and Scrapie in sheep. TSEs are characterised by the conversion of a normal host protein into a pathogenic protein within

the brain tissue of an infected animal. The pathogenic form of protein is often referred to as a prion and is highly resistant to physical and chemical degradation. The prion is believed to be the transmissible agent through which the TSE disease is passed on between animals. As now claimed, the invention includes a method for inactivating a transmissible spongiform encephalopathy (TSE) agent, comprising exposing the TSE agent to a thermostable proteolytic enzyme, wherein the TSE agent is a prion, and wherein the prion is exposed to the thermostable proteolytic enzyme at a temperature that is equal to or greater than 40° C.

Applicants respectfully submit that the claim rejections under 35 U.S.C. § 103 as being obvious over Shenoy et al. (U.S. Patent No. 5,756,678) in view of Daniels et al. have been obviated by appropriate amendment. The cited references, either alone or in combination, do not teach or suggest exposing the TSE agent to a thermostable proteolytic enzyme at a temperature that is equal to or greater than 40° C.

Shenoy et al. describes a method of inactivating prions by exposing collagen to NaOH and the use of NaOH to inactivate prions contained therein (for example, see claims 1 and 17). Proteolytic enzymes are used to remove telopeptides from collagen to produce solubilized, atelopeptide collagen (see, for example, col. 15, lines 11-46). Shenoy et al. does not describe exposing the TSE agent to a thermostable proteolytic enzyme at a temperature that is equal to or greater than 40° C.

Daniels et al. reviews proteolytic enzymes, particularly thermostable enzymes. It does not describe the use of thermostable enzymes to inactivate prions.

The claimed invention is a method for inactivating a transmissible spongiform encephalopathy (TSE) agent, including exposing the prion to the thermostable proteolytic enzyme at a temperature that is equal to or greater than 40° C. Shenoy et al. describes use of proteolytic enzymes to remove telopeptides from collagen prior to the inactivation of prions with NaOH. Daniels et al. is a review of proteolytic enzymes. Neither Shenoy et al. nor Daniels et al., either alone or in combination, teaches or suggests exposing the TSE agent to a thermostable proteolytic enzyme at a temperature that is equal to or greater than 40° C. Applicants submit that the claimed

invention is not obvious over these references. Withdrawal of the claims rejections is respectfully requested.

Applicants submit that the application is in condition for allowance. Early notice of such action is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel W. Celandor", written over a horizontal line.

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